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Suspected Transfusion Reaction Process

Purpose

This document describes the responsibilities of the various departments (clinical services, laboratory etc.) involved in the detection, reporting and investigation of suspected transfusion reactions

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Policy

- All staff involved in ordering and administering transfusions must be able to recognize a transfusion reaction.
- When a suspected transfusion reaction is observed, the unit being transfused at that time must be disconnected, unless the reaction is an urticarial reaction.
- The attending or ordering physician and the laboratory must be notified as soon as possible of the suspected transfusion reaction (immediately after taking care of the patient).
- The investigation of suspected transfusion reactions must be initiated as soon as possible by the transfusion service laboratory, and if the results of testing confirm the transfusion reaction, the attending physician must be notified immediately, for any abnormal result as defined in "*How to Investigate a Suspected Transfusion Reaction*"
- Transfusion associated fatalities are reported to the FDA/CBER within 24 hours, with a written report to follow within seven days.
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Suspected Transfusion Reaction Process, Continued

Procedure

Recognition and reporting of the suspected transfusion reaction: Attending physician and/or nursing staff

Step	Action
1.	Recognize a suspected transfusion reaction. • Symptoms are listed on the back of the *Transfusion Reaction: Investigation of Suspected Reaction* form. • Blood Transfusion and Respiratory Distress (Attachment A) can be used to differentiate TRALI from TACO
2.	Assess the reaction, and stop the transfusion immediately. • Complete steps 1-4 specified on the NURSING PROCEDURES IMMEDIATE STEPS found on the *Transfusion Reaction: Investigation of Suspected Reaction* form.
3.	Carefully assess the reaction:
4.	Immediately perform clerical check: • Compare information on the blood product bag, transfusion tag, and patient's armband. • Sign the form indicating that the check occurred and mark "agree" or "disagree".
5.	Promptly notify (by phone) the attending physician and the transfusion service (Laboratory).
6.	For all cases • Have an order for Transfusion Reaction Workup placed in Health Connect (213123) • Obtain properly labeled EDTA specimen **STAT** from patient avoiding hemolysis (except for minor skin rashes or mild hives):.

If the suspected reaction is	Then
Mild urticarial	• Keep the infusion lines connected.
All others	• Disconnect the blood product • Maintain the line with normal saline

Suspected Transfusion Reaction Process, Continued

Procedure continued

Step	Action
7.	Complete the TRANSFUSION RECORD portion of the *Transfusion Reaction: Investigation of Suspected Reaction* form. • Time Started • Reaction Date and Time • Time Infusion Stopped **Note:** This is the time the infusion was stopped, not the time it was disconnected. This time should be very close to the time of the reaction. • Donor Unit Number • Volume Transfused • Product Transfused • Pre and Post Transfusion vital signs • Symptoms • Pre-medications • Reaction Noted by • Patient ID Check **Note**: Check Agree or Disagree By: RN who performed patient ID Check
8.	Send the following to the Transfusion Service (Laboratory): • Blood sample (not required for symptoms of rash/hives) • Completed *Investigation of Suspected Transfusion Reaction* form- check to make sure all the sections in the TRANFUSION RECORD section have been completed Blood product with the attached infusion set and all attached fluid bags. **Do not send the needles.**

Suspected Transfusion Reaction Process, Continued

Procedure

Laboratory investigation of the suspected transfusion reaction: Transfusion Service	
Step	**Action**
1.	The call from the nursing service or attending physician is recorded in the laboratory.
2.	If the expected blood sample is not received in the laboratory within one hour from the initial call, the location reporting the reaction is called to resolve the problem.
3.	The following checks and tests are performed immediately: • Perform a clerical check • Centrifuge the sample and observe for hemolysis and/or icterus The following tests are performed on the transfusion reaction sample as indicated: • ABO Rh of post-transfusion sample. Direct antiglobulin test (DAT)

Suspected Transfusion Reaction Process, Continued

Procedure continued

<table>
<tr><th>Step</th><th colspan="2">Action</th></tr>
<tr><td>4.</td><td colspan="2">The technologist (CLS) reviews the above results:</td></tr>
<tr><td></td><td>IF any result is</td><td>THEN</td></tr>
<tr><td></td><td>Abnormal (as defined in How to Investigate a Suspected Transfusion Reaction SOP</td><td>• Notify the patient's physician or attending physician and the Transfusion Service Medical Director immediately.
• Proceed with the investigation (see How to Investigate a Suspected Transfusion Reaction).</td></tr>
<tr><td></td><td>Normal</td><td>• Complete the information in the computer system.
• Send the report to the Transfusion Service Medical Director for review.
• Additional units may be issued if requested.</td></tr>
<tr><td>5.</td><td colspan="2">When abnormal laboratory results are found, the Transfusion Service Medical Director must complete an evaluation.
• If the physician requests additional blood and/or blood components for transfusion pending this evaluation, they will be dispensed on an EMERGENCY release basis.
An emergency waiver will need to be signed by the ordering provider</td></tr>
</table>

Suspected Transfusion Reaction Process, Continued

Procedure continued

Step	Action
6.	If the decision is made by the provider to cancel the transfusion reaction workup order after the form, product, and/or sample is received.

IF	THEN
Sample received, no testing completed	• Add the test HOLD BB to the accession number. • Add result note to HOLD BB test that "Original order cancelled" • Cancel the Tx Rx Initial test (Reason: "Test Cancel at Provider's request")
Sample received, testing completed and no abnormal results found	Test will be completed with pathologist evaluation.
Sample received, testing completed and abnormal results found	Go to step 4 above. Test will be completed with pathologist evaluation.
No sample received, clerical check OK	Cancel the test Tx Rx Initial (Reason: "Test Cancel at Provider's request")
No sample received, clerical check NOT OK	Go to step 4 above, do not cancel the Tx Rx Initial Test.

In the case where the form, product, and/or sample is received by the laboratory and upon confirmation that an Transfusion Reaction Order will NOT be placed by the provider, document on form "No transfusion reaction ordered by Provider" and file per local protocol.
Notify manager or designee.

Suspected Transfusion Reaction Process, Continued

Procedure

Completion and review of the report	
Step	**Action**
1.	The Transfusion Service Medical Director enters his/her evaluation and comments of the Transfusion Reaction in the computer system and records them on the Suspected Transfusion Reaction form and returns the form to the Transfusion Service.
2.	Additional serological tests may be performed as directed.
3.	For suspected TRALI evaluations the blood supplier will be notified. All documents will be retained in the transfusion service with the original completed *Investigation of Suspected Transfusion Reaction* form.
4.	The original report is filed in the Transfusion Service. • The results are sent electronically at the time the Transfusion Service Medical Director verifies the evaluation in the computer system • The completed *Investigation of Suspected Transfusion Reaction* form may be faxed (or sent by another local process) by the transfusion service to the provider A copy of the completed report is also sent to be scanned into the patient chart (Health Connect).

Procedure

When to report a transfusion related fatality to FDA/CBER	
Step	**Action**
1.	Record any reported transfusion related fatality on a Suspected Transfusion Reaction form.
2.	The transfusion service medical director, often in consult with the attending physician reviews the report.

Suspected Transfusion Reaction Process, Continued

Procedure Continued

Step	Action
3.	The report is reviewed to determine the role transfusion played in the death of the patient

IF	THEN
The underlying disease state was attributed to death	• Do **NOT** report to FDA/CBER • Document cause of death on the form, sign and file. • Depending on the judgement of the medical director, discussions may occur with the local QI or QA department.
The death was definitely attributable to the transfusion **OR** the transfusion was deemed likely (by the evaluation of the Transfusion Service Medical Director or designee) to have contributed significantly to the death of the patient	• Discuss the case with your local QI or QA department, and initiate a report as advised. • Report to the RCBBO and FDA/CBER

Note: The Transfusion Service Medical Director or designee reviews the case and decides if the transfusion was involved in the patient's death. Part of this review could be discussions with the QI or QA departments.

Suspected Transfusion Reaction Process, Continued

Procedure

Reporting Fatalities to FDA/CBER	
Step	**Action**
1.	Initial notification is required as soon as possible after a complication of transfusion is confirmed to be fatal. Include the following information: • Date and time of the notification (if not via e-mail) • Your name, title, telephone number, and fax (if available) • The facility name, mailing address, and FDA registration number (if applicable) • Age and sex of the deceased • Date, time, and cause or suspected cause of death • If an autopsy was or will be performed. • Transfusion date(s) • Blood/blood component(s) and unit numbers(s) of product(s) that may be implicated. • Name and address of facilities providing the blood • Brief description of event that led to the fatality (ie underlying medical condition, reason for transfusion, etc)
2.	A 7 day report is required within 7 days after the fatality and must include new findings or information and the follow-up investigation and conclusions. Include the following information if not provided in the initial notification: • •Discharge summary and/or death certificate • •Autopsy report (if performed) • •Conclusions and follow-up actions (corrective action plan) This report may be amended by filing additional information as it becomes available.

Suspected Transfusion Reaction Process, Continued

Procedure continued

Step	Action
3.	The notification and/or reports can be submitted to: • E-mail: fatalities2@cber.fda.gov • Telephone: 301-827-6220 • Fax: 310-827-6748, Attn CBER Fatality Program Manager • Mail: Office of Compliance and Biologics Quality/CBER Attn:Fatality Program Manager 1401 Rockville Pike, Suite 200N Rockville, MD 20852-1448

Non-Controlled Documents

Attachment A: Blood Transfusion and Respiratory Distress

Controlled Documents

AABB Standards, current ed.
CAP Requirements, checklist, current ed.
Fung, Mark K. Ed. Technical Manual, 18th Ed. AABB ,2014
Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; FDA, Sept, 2003.

Suspected Transfusion Reaction Process, Continued

Reviewed and approved by:

Previously signed	September 18, 2000
Virginia Vengelen-Tyler, MBA, MT,ASCP(SBB), CQA(ASQ) Regional Blood Bank Compliance Officer	Date
Signature Collected Electronically	January 5, 2011
Adriana A. Bedoya, M.D. FCAP, FASCP Medical Director- San Diego –SA	Date
Signature Collected Electronically	September 14, 2000
Gary Gochman, MD, Medical Director – Bellflower, Harbor City, Baldwin Park MSA	Date
Signature Collected Electronically	August 20, 2010
Jeffrey D. Shiffer, MD. Medical Director –San Fernando Valley SA	Date
Signature Collected Electronically	August 25, 2000
Joseph Thompson, MD. Medical Director –Los Angeles, West Los Angeles MSA	Date
Signature Collected Electronically	August 21, 2006
David R. Huebner-Chan, MD. Medical Director –Orange County SA	Date
Signature Collected Electronically	August 16, 2000
Dong Quach, MD. Medical Director –Riverside, Fontana MSA	Date

Suspected Transfusion Reaction Process, Continued

DOCUMENT HISTORY PAGE

Effective Date: July 22, 1999

Change type: new, major, minor etc.	Changes Made to Document – Describe	Signature responsible person/Date	Med. Dir. Reviewed/ Date
Major	Process taken from QSE:7-0400. Includes nursing, lab and pathology processes.	Ginny Tyler 09-18-00	
Major Ver.0.2	1)Revised the form. 2) Removed the CLS contacting attending MD on Neg. work-up.	Ginny Tyler 5-11-01	
Minor	Removed Volume overload from list to keep line open.	Ginny Tyler 12/22/06	N.A.
Minor	1. Added references to the electronic forms being used in place of the TS form. 2. Added ILIDS-TS entry of results, and reviews. 3. Corrected the retention of records from indefinite to 5 years.	Ginny Tyler 01/27/08	N.A.
Minor	Added COLA to the facilities section.	Ginny Tyler 05/22/08	N.A.
Minor	• Added ABO typing back – somehow was removed from previous versions. • Added comments to complete paper form, needs to be sent to record room.	Ginny Tyler 11/20/08	N.A. (was discussed at TM meeting Sept. 08)

Suspected Transfusion Reaction Process, Continued

MasterControl History of Change:		
Change type: new, major, minor etc.	**Version #**	**Description of Change**
Major	8	Removed COLA Added Attachment A Added FDA/CBER notification steps if a fatality occurs Updated Uncontrolled and Controlled Documents
Minor	9	Added Health Connect order name for Transfusion Reaction to Step 6 in physician/nursing staff section. Clarified steps 3 and 5 in laboratory investigation section. Added step 6 in laboratory investigation regarding cancellation of workups.

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Suspected Transfusion Reaction Process, Continued

ATTACHMENT A:
BLOOD TRANSFUSION AND RESPIRITORY DISTRESS

Acute onset
Dyspnea
Tachycardia
Pulmonary edema

Transfusion Related Acute Lung Injury (TRALI)	Transfusion Associated Circulatory Overload (TACO)
BP: Decreased	BP: Increased
Chest XR: Non-cardiogenic pulmonary edema (bilateral whiteout)	Chest XR: Pulmonary edema with cardiac symptoms
Mechanism: Immune mediated	Mechanism: Volume related
Management: Oxygen therapy	Management: Diuretics, O2 therapy
Prevention: Identification and elimination of blood donors implicated in TRALI cases.	Prevention: Patients at risk should receive transfusion slowly with attention to total fluid

IMMEDIATE ACTIONS:

- Stop the transfusion.
- Call physician.
- Call Blood Bank.
- Send infusion set along with any solution attached to the bag and a fresh blood sample to the Blood Bank.

Fill out Investigation of Suspected Transfusion Reaction form and send to the Blood Bank for workup.